SEP 27 2013

510(k) Summary

Submitter information

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Submission date

The date of the Traditional 510(k) submission is May 27th, 2013.

Submission information

Trade Name	Match Point System™, Match Point System™ guide, SurgiCase Connect
Common Name	Patient specific instrumentation for shoulder arthroplasty
Classification Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
Product codes	KWS

Predicate devices

Trade or proprietary or model name	Signature Personalized Patient Care System – Acetabular Guide System
510(k) number *Decision date* *Product codes* *Manufacturer*	K111863 06/15/2012 JDI, KWY, KWZ, LPH, LZO, MAY, MEH Materialise NV

Conventional instrumentation for shoulder arthroplasty (central drill guide) predicate:

510(k) number	Decision date	Product code	Trade or proprietary or model name	Manufacturer
K051075	05/27/2005	KWS	Encore Shoulder System	Encore Medical, L.P.
K080402	03/28/2008	KWS	Turon™ Shoulder System	Encore Medical, L.P.
K111629	09/16/2011	KWS	Turon™ to RSP Conversion Shell	Encore Medical, L.P.
K092873	10/27/2009	KWS	Reverse® Shoulder prosthesis	DJO Surgical

Device Information

Description of the device

The **Match Point System™** consists of a software component, SurgiCase Connect and a hardware component, Match Point System™ guide, and is designed to assist the surgeon in the placement of glenoid components.

The **Match Point System** is for use within the intended use of the compatible components.

Functioning of the device

The **Match Point System** generates a preoperative plan based on medical imaging data using SurgiCase Connect, the software component. This software is used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the preoperative plan. The preoperative plan displays a virtual 3D model of the patient's scapula, a glenoid implant for either reverse or total shoulder replacement positioned onto the glenoid surface, and the central pin which corresponds to the glenoid implant's position. The implant and pin are initially displayed in a default location according to the surgical technique of the respective implant system. The surgeon modifies the default position by rotating and translating the pin and implant orientation. Once the implant is in the desired position, the surgeon approves the preoperative plan.

Once approved, a **Match Point System guides** is designed and manufactured based on the preoperative plan. **Match Point System guides** are patient specific templates that transfer the preoperatively approved pin positioning to the patient intraoperatively. The guide consists of a patient specific baseplate which conforms to the patient's anatomy. The drill cylinder's position corresponds to the planned drill position. This drill cylinder's inner diameter matches the corresponding instrumentation's diameter. A Kirschner wire may be optionally used to help stabilize the guide's position while drilling.

Intended use

The **Match Point System™** is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty procedures which utilize anatomic landmarks that are identifiable on preoperative CT or MRI medical images.

The **Match Point System™** can be used with the following total and reverse shoulder implant systems and their respective compatible components: Encore Shoulder System (K051075), Turon™ to RSP Conversion Shell (K111629), Turon™ Shoulder System (K080402) and Reverse® Shoulder prosthesis (K092873).

The **Match Point System™ guides** are intended for single use only.

Summary of technological characteristics

Device comparison analysis showed that the proposed device is substantially equivalent to the predicate devices in:

- design, intended use, functionality, technology, material and performance characteristics for the Signature Personalized Patient Care System – Acetabular Guide System;
- intended use and functionality for the conventional instrumentation for shoulder arthroplasty (central drill guide).

Performance data

Non-clinical tests

Accuracy performance testing was performed in a cadaveric setting to determine substantial equivalence. Testing verified that the accuracy and performance of the system is adequate to perform as intended. Accuracy performance testing was performed on rapid prototyped models to verify guide use, positioning, and accuracy of the shoulder system at its borders for use.

Clinical data

Non-clinical testing was sufficient to demonstrate safety and effectiveness of the device as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Materialise N.V.
Ms. Alexandra Razzhivina
Regulatory Officer
Technologielaan 15
Leuven 3001
Belgium

Re: K131559
Trade/Device Name: Match Point System™ (Match Point System™ Guides, SurgiCase Connect)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS
Dated: September 16, 2013
Received: September 18, 2013

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): unknown K131559

Device Name: Match Point System™ (**Match Point System™ Guides, SurgiCase Connect**)

Indications for Use:

The **Match Point System™** is intended to be used as a surgical instrument to assist in the intraoperative positioning of glenoid components used with total and reverse shoulder arthroplasty procedures which utilize anatomic landmarks that are identifiable on preoperative CT or MRI medical images.

The **Match Point System™** can be used with the following total and reverse shoulder implant systems and their respective compatible components: Encore Shoulder System (K051075), Turon™ to RSP Conversion Shell (K111629), Turon™ Shoulder System (K080402) and Reverse® Shoulder prosthesis (K092873).

The **Match Point System™ Guides** are intended for single use only.

Prescription Use _ X ____ AND/OR Over-The-Counter Use __ _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices